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**उत्पाद मैनुअल**  
**RESPIRATORY PROTECTIVE DEVICES–**  
**FILTERING HALF MASKS TO PROTECT AGAINST PARTICLES**

**IS 9473:2002 के अनुसार**

**PRODUCT MANUAL FOR**  
**RESPIRATORY PROTECTIVE DEVICES–**  
**FILTERING HALF MASKS TO PROTECT AGAINST PARTICLES**

**According to IS 9473:2002**

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना- I के तहत प्रमाणन के संचालन में अभ्यास और पारदर्शिता के संचालन में पारदर्शिता सुनिश्चित करने के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन लाइसेंस/प्रमाणपत्र प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

*This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.*

|    |                                                                  |   |                                                                                                                                                                                                                                                                                                                                      |
|----|------------------------------------------------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. | उत्पाद<br>Product                                                | : | IS 9473:2002                                                                                                                                                                                                                                                                                                                         |
|    | शीर्षक<br>Title                                                  | : | Respiratory protective devices – filtering<br>Half masks to protect against particles- specification                                                                                                                                                                                                                                 |
|    | संशोधनों की संख्या<br>No.of amendments                           | : | 01                                                                                                                                                                                                                                                                                                                                   |
| 2. | नमूना दिशानिर्देश<br>Sampling Guidelines                         |   |                                                                                                                                                                                                                                                                                                                                      |
| a) | कच्चा माल<br>Raw material                                        | : | Material of filtering half masks shall conform to the requirements given in 5.1. 5.2, and 5.5 of IS 9473:2002 (For compliance to 5.1.4 (Metal), 5.2 (Cleaning and disinfecting -applicable for multiple use masks) and 5.5 (compatibility with skin) an undertaking/declaration of conformity may be obtained from the manufacturer) |
| b) | समूहीकरण दिशानिर्देश<br>Grouping Guidelines                      | : | Please refer ANNEX- A                                                                                                                                                                                                                                                                                                                |
| c) | नमूने का आकार<br>Sample Size                                     | : | 70 numbers                                                                                                                                                                                                                                                                                                                           |
| 3. | निरीक्षण और परीक्षण की स्कीम<br>Scheme of Inspection and Testing | : | Please refer ANNEX –B                                                                                                                                                                                                                                                                                                                |

|    |                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                   |                       |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| 4. | <b>Scheme of Inspection and Testing</b>                                                                                                                                                                                                                                                          | :                                                                                                                                                                 | Please refer ANNEX –C |
| 5. | <b>एक दिन में संभावित परीक्षण<br/>Possible tests in aday</b>                                                                                                                                                                                                                                     |                                                                                                                                                                   |                       |
|    | Visual Inspection, Practical performance test (AR), Filter Penetration (AR), Flammability (AR), Carbon Dioxide Content of the inhalation air, Field of vision, Exhalation valve pull Total inward leakage (AR), Exhalation valve flow (AR), Exhalation valve pull (AR), Breathing resistance AR) |                                                                                                                                                                   |                       |
| 6. | <b>Scope of the Licence :</b>                                                                                                                                                                                                                                                                    |                                                                                                                                                                   |                       |
|    | “Licence is granted to use Standard Mark as per IS 9473:2002 with the following scope:                                                                                                                                                                                                           |                                                                                                                                                                   |                       |
|    | Name of the product                                                                                                                                                                                                                                                                              | Respiratory protective devices – filtering Half masks to protect against particles- specification                                                                 |                       |
|    | Class                                                                                                                                                                                                                                                                                            | Class FFP1/FFP2/FFP3                                                                                                                                              |                       |
|    | Sub-Class                                                                                                                                                                                                                                                                                        | S (Solid) / SL (Solid and Liquid)                                                                                                                                 |                       |
|    | Type                                                                                                                                                                                                                                                                                             | With / without Valves; For single use/multiple use                                                                                                                |                       |
|    | Clogging                                                                                                                                                                                                                                                                                         | Without resistance to clogging /With resistance to clogging for use in mining applications /With resistance to clogging for use in other than mining applications |                       |

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## **ANNEX A**

### **GROUPING GUIDELINES**

Following grouping guidelines shall apply while defining the scope of the licence in case of application for grant of licence or application for change in scope of licence

1. If higher class filtering half mask is tested, lower class may be considered with same configuration. i.e.,
  - a. If FFP3 sample is tested, FFP1 & FFP2 may also be covered.
  - b. If FFP2 sample is tested, FFP1 may also be covered.
2. If subclass SL (Solid and Liquid) is tested, subclass S (Solid) may also be covered.
3. If sample with valves is tested, without valves also may be covered
4. If sample not for single use (multiple use) only is tested, single use only product also may be covered.

However, it shall be ensured that the firm has the requisite manufacturing and testing facilities to produce the varieties intended to be covered in the scope of licence

During operation of licence, samples of all varieties shall be drawn and tested by rotation.

**ANNEX B**  
**List of Test Equipment**

***Major test equipment required to test as per the Indian Standard***

| Sl. No. | Tests used in with Clause Reference                             | Test Equipment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|---------|-----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1       | Material CI 5.1                                                 | <p><b><u>Conditioning</u></b></p> <ol style="list-style-type: none"> <li><b>Simulated Wearing Treatment</b> set up as per A-1.1 including a Breathing Machine, Sheffield Dummy Head, saturator incorporated in the exhalation line between the breathing machine and dummy head, excess water collection trap and a thermometer.</li> <li><b>Temperature Conditioning</b> set up as per A-1.2—oven and freezer capable of subjecting filtering half masks to following thermal cycles: <ol style="list-style-type: none"> <li>For 24 h to a dry atmosphere of <math>70\pm3^{\circ}\text{C}</math></li> <li>For 24 h to a temperature of <math>-30\pm3^{\circ}\text{C}</math></li> </ol> </li> </ol> |
| 2       | Practical performance test, Cl. 5.3                             | <ul style="list-style-type: none"> <li><b>Walking Test as per A-2.1:</b> Level course, stopwatch, means to measure the rate(speed) of subjects during the test</li> <li><b>Work Simulation Test as per A-2.2:</b> level course for walking with a headroom of <math>1.3\pm0.2\text{m}</math>, level course for crawling with a headroom of <math>0.7\pm0.05\text{m}</math>, Small (8 l) basket, rubber chippings, 1.5m high hopper, shovel etc as per Fig 1 of IS 9473:2002</li> </ul>                                                                                                                                                                                                              |
| 3       | <b>Leakage, CI 5.4</b><br>Total inward leakage, Cl.5.4.1        | <ul style="list-style-type: none"> <li><b>Sodium Chloride (NaCl) Method:</b> Test enclosure and apparatus for the determination of inward leakage using sodium chloride incorporating Level Treadmill capable of working at 6 km/h, NaCl aerosol generator, test agent, sampling probe, sample pump, pressure detection probe, manometer, flame photometer, sample selector etc. (See Fig 3 of IS 9473:2002 for a typical apparatus)</li> </ul>                                                                                                                                                                                                                                                     |
| 4       | <b>Leakage, CI 5.4</b><br>Penetration of filter media Cl, 5.4.2 | <p><b>Short term and full exposure penetration tests as per IS 17274 (Part 3)</b></p> <p>Reference aerosols - Sodium Chloride (solid aerosol) and paraffin oil (liquid aerosol) as per IS 17274 (Part 3)</p> <ul style="list-style-type: none"> <li>Test apparatus for determination of particle filter penetration consisting of four modules: aerosol generator, flow control, filter test chamber and aerosol detector as per IS 17274 (Part 3)</li> </ul>                                                                                                                                                                                                                                       |
| 5       | Flammability CI 5.6                                             | <ul style="list-style-type: none"> <li>Test rig for flammability as per Annex E of IS 14166 consisting of propane storage tank with control device and fine pressure gauge, flash back</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

|    |                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----|-------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |                                                                                                             | <p>arrester, one Bunsen burner (instead of 6 given in Annex E of IS 14166) adjustable in height.</p> <ul style="list-style-type: none"> <li>- Metallic dummy head with motorization arrangement capable of describing a horizontal circle with variable control speed.</li> <li>- Thermometer/Temperature measuring device to record flame temperature</li> </ul>                                                                                                                          |
| 6  | Carbon Dioxide Content of the inhalation air, Cl 5.7                                                        | <p>Apparatus consisting of</p> <ul style="list-style-type: none"> <li>- Breathing machine with solenoid valves controlled by the breathing machine, a connector, a CO2 flow meter, a CO2 analyser and a humidifier</li> <li>- Dummy Head (Type Sheffield)</li> <li>- CO2 absorber</li> <li>- Control valve, flow meter, compensating bag and non return valves through which CO2 is fed into breathing machine</li> </ul> <p>Typical test arrangement given in Fig. 16 of IS 9473:2002</p> |
| 7  | Head Harness, Cl. 5.8                                                                                       | Apparatus as given above for Practical Performance Test (A-2) and Leakage Test (A-3)                                                                                                                                                                                                                                                                                                                                                                                                       |
| 8  | The field of vision, Cl. 5.9                                                                                | Apertometer (Field of Vision), Facepiece, dummy head                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 9  | Inhalation and Exhalation Valves, Cl 5.10                                                                   | <p>1) Temperature Conditioning set up as per A-1.2– oven and freezer capable of subjecting filtering half masks to thermal cycles</p> <p>2) Apparatus as given above for Leakage Test (A-3)</p> <p>3) Mechanical Strength test apparatus as per Fig 23</p> <p>4) Fixture as per Fig 18 and Arrangement to apply an axial force of 10 N</p>                                                                                                                                                 |
| 10 | Breathing resistance of the valved&valveless filtering masks, Cl. 5.11                                      | Breathing Resistance Rig as per Fig 15, Dummy Head type Sheffield), breathing machine,, flow meter, stop watch, barometer/pressure indicator/pressure transducer                                                                                                                                                                                                                                                                                                                           |
| 11 | <p>Clogging, Cl 5.12</p> <p>i) CoalDust</p> <p>ii) Dolomite Dust</p> <p>(Optional for single use masks)</p> | <p><b>1) Clogging test using coal</b></p> <ul style="list-style-type: none"> <li>- Coal Dust (Ball mill and 240 mesh sieve for grinding and grading the coal dust)</li> <li>- Clogging test apparatus (Fig. 19)</li> </ul> <p><b>2) Clogging test using dolomite dust</b></p> <ul style="list-style-type: none"> <li>- DUST:DRB 4/15 dolomite</li> <li>- Clogging test apparatus (Fig. 20)</li> </ul>                                                                                      |
| 12 | Mechanical Strength                                                                                         | Mechanical strength test apparatus as per Fig. 23 which consists of a steel case (K) which is fixed on a vertically moving piston (S), capable of being lifted up 20 mm by a rotating cam (N) and dropping down onto a steel plate (P) due to its own mass as the cam rotates. The mass of the steel case shall be more than 10 kg                                                                                                                                                         |

|    |                                                             |  |
|----|-------------------------------------------------------------|--|
| 13 | Air Conditioner to maintain Temperature and humidity in lab |  |
|----|-------------------------------------------------------------|--|

Note 1: Wherever applicable, equivalent automated instruments validated against the corresponding test methods prescribed in Annex A may be used. For total inward leakage, even if an automated instrument is used, the test subject shall follow the exercises prescribed in A-3

Note 2: Test subjects shall be chosen as defined in the relevant clauses of the Indian Standard.

Note 3: The above list is indicative only and may not be treated as exhaustive.

## **ANNEXURE-C**

### **SCHEME OF INSPECTION AND TESTING**

**1. LABORATORY** - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test equipment.

**2. TEST RECORDS** –The manufacturer shall maintain test records for the tests carried out to establish conformity.

**3. PACKING AND MARKING**– The Standard Mark as given in the Schedule of the licence, shall be suitably marked on each half filter masks and its container, provided always that the half filter masks to which this mark is thus applied, conform to every requirement of the specification.

3.1 Packing and marking shall be done as per the requirements of IS 9473:2002. In addition, the following shall be marked on each half filter mask or its container:

- i) BIS Licence No, CM/L-
- ii) BIS website details: For BIS certification details visit [www.bis.gov.in](http://www.bis.gov.in)

3.2 **INSTRUCTION FOR USE** – Instructions for use as given in IS 9473:2002 shall be supplied in English and Hindi/the local language with every half filter mask marked with Standard Mark.

**4. CONTROL UNIT** - For the purpose of this scheme, all filtering half masks of the same class/variety produced in one day **from the same material** shall be considered as a control unit.

**5. LEVELS OF CONTROL** - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

5.1 In case of failure in any requirements the entire control unit shall not be marked with the Standard mark. After the cause of failure is investigated and necessary corrective actions taken, the Filtering half masks in a control unit of 1000 nos. with improvements incorporated therein shall be tested as per the levels of control on the full control unit and the marking shall be resumed only if these Filtering half masks satisfy with all the requirements of the specification. The Bureau shall be kept informed at every stage.

5.2 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

**6. REJECTIONS**–Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

**TABLE 1**  
**LEVELS OF CONTROL**

| (1)          |                                             |                             |           | (2)                                                                         | (3)                          |                                    |           |
|--------------|---------------------------------------------|-----------------------------|-----------|-----------------------------------------------------------------------------|------------------------------|------------------------------------|-----------|
| Test Details |                                             |                             |           | Test equipment requirement<br>R: required (or) S: Sub-contracting permitted | Levels of Control            |                                    |           |
| Cl.          | Requirement                                 | Test Methods                |           |                                                                             | No. of Sample (Condition)    | Frequency                          | Remarks   |
|              |                                             | Clause                      | Reference |                                                                             |                              |                                    |           |
| 5.13         | Visual Inspection                           | A-11                        | IS 9473   | R*                                                                          | All (AR)                     | -                                  | See Notes |
| 5.1, 5.5     | Material , Material compatibility with skin | A-11                        | -do-      | R*                                                                          | 3 (SW)                       | Every 7 <sup>th</sup> control unit |           |
|              |                                             |                             |           |                                                                             | 3 (TC)                       | -do-                               |           |
| 5.2          | Cleaning and disinfection                   | Manufacturer's instructions | -do-      | R*                                                                          | 5 (AR)                       | Once a year                        |           |
| 5.3          | Practical Performance                       | A-2                         | -do-      | R*                                                                          | 2 (AR)                       | -do-                               |           |
| 5.4          | Leakage Test                                |                             |           |                                                                             |                              |                                    |           |
| 5.4.1        | Total inward leakage                        | A-3#                        | -do-      | R*                                                                          | 5 (AR)                       | Once a year                        |           |
|              |                                             |                             |           |                                                                             | 5 (TC)                       | -do-                               |           |
| 5.4.2        | Filter Penetration                          | A-4#                        | -do-      | R*                                                                          | 3 (AR) – for each aerosol    | Every 7 <sup>th</sup> control unit |           |
|              |                                             |                             |           |                                                                             | 3 (SW) – for each aerosol    | Once a year                        |           |
|              |                                             |                             |           |                                                                             | 3 (MS+TC) – for each aerosol | -do-                               |           |
| 5.6          | Flammability                                | A-5                         | -do-      | R*                                                                          | 2 (AR)                       | Once a year                        |           |

|                    |                                           |                    |          |    |                                                                   |                                    |        |
|--------------------|-------------------------------------------|--------------------|----------|----|-------------------------------------------------------------------|------------------------------------|--------|
|                    |                                           |                    |          |    | 2 (TC)                                                            | -do-                               |        |
| 5.7                | CO <sub>2</sub> content of inhalation air | A-6#               | -do-     | R* | 3 (AR)                                                            | Every 7 <sup>th</sup> control unit |        |
| 5.8                | Head harness                              | 5.8                | -do-     | R* | To be done along with practical performance test and leakage test |                                    |        |
| 5.9                | Field of vision                           | A-2 & A-8          | IS 14746 | R* | 2 (AR)                                                            | Once a year                        |        |
| 5.10.2.1, 5.10.2.2 | Exhalation valve                          | 5.10.2.1, 5.10.2.2 | IS 9473  | R* | To be done along with leakage test                                |                                    |        |
| 5.10.2.3           | Exhalation valve flow                     | 5.10.2.3 (FC)      | IS 9473  | R* | 1 (AR)                                                            | Every 7 <sup>th</sup> control unit |        |
|                    |                                           |                    |          |    | 2 (TC)                                                            | Once a year                        |        |
| 5.10.2.4           | Exhalation valve pull                     | A-7                | -do-     | R* | 1 (AR)                                                            | Every 7 <sup>th</sup> control unit |        |
|                    |                                           |                    |          |    | 1 (MS)                                                            | Once a year                        |        |
|                    |                                           |                    |          |    | 1 (TC)                                                            | Once a year                        |        |
| 5.11               | Breathing resistance (valved)             | A-8#               | -do-     | R* | 3 (AR)                                                            | Every 7 <sup>th</sup> control unit |        |
|                    |                                           |                    |          |    | 3 (SW)                                                            | Once a year                        |        |
|                    |                                           |                    |          |    | 3 (TC)                                                            | Once a year                        |        |
|                    |                                           |                    |          |    | 3 (FC)                                                            | Once a year                        |        |
| 5.11               | Breathing resistance (valveless)          | A-8#               | -do-     | R* | 3 (AR)                                                            | Every 7 <sup>th</sup> control unit |        |
|                    |                                           |                    |          |    | 3 (SW)                                                            | Once a year                        |        |
|                    |                                           |                    |          |    | 3 (TC)                                                            | Once a year                        |        |
| 5.12               | Clogging (Optional for single-use masks)  | A-9<br>A-8#<br>A-4 | -do-     | R* | 1 (AR)                                                            | Once a year                        |        |
|                    |                                           |                    |          |    | 1 (TC)                                                            | Once a year                        |        |
| 6,7                | Packing/markings and Instructions for use | 6,7                | -do-     | R  | One                                                               | Each control unit                  | Visual |

- a) Most samples are used for more than one test
- b) Conditioning abbreviations:
  - AR – As received
  - SW – Simulated wearing treatment
  - TC – Temperature conditioned
  - FC – Flow conditioned

Note 1 : Whenever there is a change in the design or material, compliance to all the requirements of the standards to be ensured by carrying out all the tests as per IS 9473 and product shall be marked only after conformity has been established. This testing may be conducted either in-house or in the factory of a BIS licensee (with that variety covered in their scope) or laboratory established or recognized by the Bureau or Government laboratories empaneled by the Bureau

\*Note 2: Sub-contracting is permitted for these tests only if the manufacturer has applied for grant of licence or addition in scope of licence for FFP2 Masks and **only up to 31 March 2023** subject to the condition that ISI Marked FFP2 marks shall be supplied only to HLL Lifecare/Govt of India. Subcontracting may be done to a laboratory of a BIS licensee (whose scope covers the variety to be tested), or a laboratory established or recognized by the Bureau or Government laboratories empaneled by the Bureau

Note 3: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/control unit/lot and submit his own levels of control in column 3 with proper justification to BO head.

Note 4: Conformity of the materials to the requirements of the standard may be established either through the supplier/manufacturer's test certificate, or test report issued by BIS lab/BIS recognized Lab/BIS Empanelled Lab or through in-house testing

**#Note 5: Wherever applicable, equivalent automated instruments validated against the corresponding test methods prescribed in Annex A may be used. For total inward leakage, even if an automated instrument is used, the test subject shall follow the exercises prescribed in A-3**